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In re Application of

Platz et al

Application Number

08/246, 034

Filed

May 18, 1994

Paper No. *78*

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Registration Number, if applicable

703-415-3060

Telephone Number



US006231851B1

(12) **United States Patent**  
**Platz et al.**

(10) **Patent No.:** US 6,231,851 B1  
(45) **Date of Patent:** May 15, 2001

(54) **METHODS AND COMPOSITIONS FOR THE DRY POWDER FORMULATION OF INTERFERONS**

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(\*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.:** 08/737,724

(22) **PCT Filed:** May 15, 1995

(86) **PCT No.:** PCT/US95/06008

§ 371 Date: Jul. 14, 1997

§ 102(e) Date: Jul. 14, 1997

(87) **PCT Pub. No.:** WO95/31479

PCT Pub. Date: Nov. 23, 1995

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 08/246,034, filed on May 18, 1994.

(51) **Int. Cl.:** A61K 38/21; C07K 1/36

(52) **U.S. Cl.:** 424/85.6; 530/351; 514/2

(58) **Field of Search:** 424/85.1, 85.4, 424/85.6, 43, 46, 489, 491; 530/351, 363; 514/12, 21, 777, 776, 2; 435/70.1; 128/200.14, 200.23

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**ABSTRACT**

According to the present invention, methods and compositions are provided for spray-dried, interferon-based dry powder compositions, particularly interferon-beta. The compositions are useful for treating conditions in humans that are responsive to treatment with interferons. In particular, the methods of the present invention rely on spray drying to produce stable, high-potency dry powder formulations of interferons, including but not limited to IFN-beta. Surprisingly, it has been found that IFN-can be prepared in high potency, dry powder formulations by spray drying. Such dry powder formulations find particular utility in the pulmonary delivery of IFN.

25 Claims, No Drawings